

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SANOFI-AVENTIS and)
SANOFI-AVENTIS U.S. LLC,)
Plaintiffs,) C.A. No. 07-572 (GMS)
vs.)
ACTAVIS SOUTH ATLANTIC LLC, *et al.*,)
Defendants.)

**SUN PHARMACEUTICAL INDUSTRIES LTD.'S ANSWER
AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT**

Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") answers the plaintiff's complaint and, with regard to each correspondingly numbered paragraph, states:

Parties

1. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 1 of the Complaint, and on that basis denies such averments.

2. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 2 of the Complaint, and on that basis denies such averments.

3. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 3 of the Complaint, and on that basis denies such averments.

4. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 4 of the Complaint, and on that basis denies such averments.

5. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 5 of the Complaint, and on that basis denies such averments.

6. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 6 of the Complaint, and on that basis denies such averments.

7. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 7 of the Complaint, and on that basis denies such averments.

8. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 8 of the Complaint, and on that basis denies such averments.

9. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 9 of the Complaint, and on that basis denies such averments.

10. Sun Ltd. admits that Sun Inc. is a Michigan Corporation, with its principal place of business at 29714 Orion Ct, Farmington Hills, Michigan 48334. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the balance of the averments contained in paragraph 10 of the Complaint, and on that basis denies the balance of such averments.

11. Sun Ltd. admits that Sun Pharmaceutical Industries Ltd. is an Indian Corporation having a place of business at Acme Plaza, Andheri-Kurla Road, Andheri (E), Mumbai, India 401059. Sun Ltd. denies the remaining averments contained in paragraph 11 of the Complaint.

12. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 12 of the Complaint, and on that basis denies such averments.

13. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 13 of the Complaint, and on that basis denies such averments.

14. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 14 of the Complaint, and on that basis denies such averments.

Nature of the Action

15. Sun Ltd. admits that the plaintiffs' Complaint purports to state claims arising under the Patent Laws of the United States of America. Sun Ltd. admits that Exhibit A to the Complaint appears to be a copy of United States Patent No. 4,661,491 ("the '491 Patent"), and that Exhibit B to the Complaint appears to be a copy of United States Patent No. 6,149,940 ("the '940 Patent").

16. The averments in paragraph 16 of the Complaint are conclusions of law to which no response is required. To the extent a response is required Sun Ltd., admits that this court has subject matter jurisdiction over the claims brought in the present action.

17. The averments of paragraph 17 of the Complaint are conclusions of law to which no response is required. To the extent a response is required, Sun Ltd. admits that this Court has personal jurisdiction over it in this District for the purpose of this action. Sun Ltd. denies the averments against it to the extent they assert that Sun Ltd. committed the referenced acts of patent infringement. As to the balance of the averments, Sun Ltd. lacks knowledge or information sufficient to form a belief as to their truth or falsity, and on that basis denies such averments.

18. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 18 of the Complaint, and on that basis denies such averments.

19. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 19 of the Complaint, and on that basis denies such averments.

20. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 20 of the Complaint, and on that basis denies such averments.

21. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 21 of the Complaint, and on that basis denies such averments.

22. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 22 of the Complaint, and on that basis denies such averments.

23. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 23 of the Complaint, and on that basis denies such averments.

24. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 24 of the Complaint, and on that basis denies such averments.

25. The averments of paragraph 25 are conclusions of law to which no response is required. To the extent a response is required Sun Ltd., denied.

26. The averments of paragraph 26 are conclusions of law to which no response is required. To the extent a response is required, Sun Ltd. admits that this Court has personal jurisdiction over it in this District for the purpose of this action.

27. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 27 of the Complaint, and on that basis denies such averments.

28. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 28 of the Complaint, and on that basis denies such averments.

29. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 29 of the Complaint, and on that basis denies such averments.

30. The averments of paragraph 30 are conclusions of law to which no response is required. To the extent a response is required, Sun Ltd. admits that venue is proper in this District for the purposes of this action.

The Patents

31. Sun Ltd. admits that the '491 Patent issued on April 28, 1997, but denies that this patent was duly and legally issued. Sun Ltd. admits that this patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral.[®] Sun Ltd. is without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining averments of paragraph 31 of the Complaint, and that basis denies such averments.

32. Sun Ltd. admits that the '940 Patent issued on November 21, 2000, but denies that this patent was duly and legally issued. Sun Ltd. admits that this patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral.[®] Sun Ltd. is without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining averments of paragraph 32 of the Complaint, and on that basis denies such averments.

Acts Giving Rise to This Action

Count I- Infringement of the '491 Patent by Defendants Actavis and Par-

33. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 33 of the Complaint, and on that basis denies such averments.

34. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 34 of the Complaint, and on that basis denies such averments.

35. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 35 of the Complaint, and on that basis denies such averments.

36. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 36 of the Complaint, and on that basis denies such averments.

37. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 37 of the Complaint, and on that basis denies such averments.

38. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 38 of the Complaint, and on that basis denies such averments.

39. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 39 of the Complaint, and on that basis denies such averments.

Count II- Infringement of the '940 Patent by Defendants Actavis and Par

40. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 40 of the Complaint, and on that basis denies such averments.

41. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 41 of the Complaint, and on that basis denies such averments.

42. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 42 of the Complaint, and on that basis denies such averments.

43. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 43 of the Complaint, and on that basis denies such averments.

44. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 44 of the Complaint, and on that basis denies such averments.

45. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 45 of the Complaint, and on that basis denies such averments.

46. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 46 of the Complaint, and on that basis denies such averments.

**Count III- Infringement of the '491 Patent by Defendants
Aurobindo Ltd. and Aurobindo Inc.**

47. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 47 of the Complaint, and on that basis denies such averments.

48. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 48 of the Complaint, and on that basis denies such averments.

49. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 49 of the Complaint, and on that basis denies such averments.

50. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 50 of the Complaint, and on that basis denies such averments.

51. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 51 of the Complaint, and on that basis denies such averments.

52. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 52 of the Complaint, and on that basis denies such averments.

53. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 53 of the Complaint, and on that basis denies such averments.

**Count IV- Infringement of the '940 Patent by Defendants
Aurobindo Ltd. and Aurobindo Inc.**

54. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 54 of the Complaint, and on that basis denies such averments.

55. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 55 of the Complaint, and on that basis denies such averments.

56. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 56 of the Complaint, and on that basis denies such averments.

57. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 57 of the Complaint, and on that basis denies such averments.

58. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 58 of the Complaint, and on that basis denies such averments.

59. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 59 of the Complaint, and on that basis denies such averments.

60. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 60 of the Complaint, and on that basis denies such averments.

Count V- Infringement of the '491 Patent by Defendant Mylan

61. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 61 of the Complaint, and on that basis denies such averments.

62. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 62 of the Complaint, and on that basis denies such averments.

63. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 63 of the Complaint, and on that basis denies such averments.

64. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 64 of the Complaint, and on that basis denies such averments.

65. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 65 of the Complaint, and on that basis denies such averments.

Count VI- Infringement of the '940 Patent by Defendant Mylan

66. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 66 of the Complaint, and on that basis denies such averments.

67. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 67 of the Complaint, and on that basis denies such averments.

68. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 68 of the Complaint, and on that basis denies such averments.

69. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 69 of the Complaint, and on that basis denies such averments.

70. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 70 of the Complaint, and on that basis denies such averments.

Count VII- Infringement of the '940 Patent by Defendants Ranbaxy Ltd. and Ranbaxy Inc.

71. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 71 of the Complaint, and on that basis denies such averments.

72. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 72 of the Complaint, and on that basis denies such averments.

73. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 73 of the Complaint, and on that basis denies such averments.

74. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 74 of the Complaint, and on that basis denies such averments.

75. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 75 of the Complaint, and on that basis denies such averments.

76. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 76 of the Complaint, and on that basis denies such averments.

77. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 77 of the Complaint, and on that basis denies such averments.

Count VIII- Infringement of the '940 Patent by Defendants Sun Inc. and Sun Ltd.

78. Sun Ltd. denies the allegations of paragraph 78 of the Complaint. Sun Inc. did not file ANDA 79-057. Sun Ltd. admits the balance of the allegations of paragraph 78 of the Complaint.

79. Sun Ltd. denies the allegations of paragraph 79 of the Complaint to the extent it alleges that Sun Inc. filed ANDA 79-057. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the balance of the averments contained in paragraph 79 of the Complaint, and on that basis denies such averments.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

Count IX- Infringement of the '491 Patent by Defendant Teva

85. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 85 of the Complaint, and on that basis denies such averments.

86. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 86 of the Complaint, and on that basis denies such averments.

87. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 87 of the Complaint, and on that basis denies such averments.

88. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 88 of the Complaint, and on that basis denies such averments.

89. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 89 of the Complaint, and on that basis denies such averments.

Count X- Infringement of the '940 Patent by Defendant Teva

90. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 90 of the Complaint, and on that basis denies such averments.

91. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 91 of the Complaint, and on that basis denies such averments.

92. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 92 of the Complaint, and on that basis denies such averments.

93. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 93 of the Complaint, and on that basis denies such averments.

94. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 94 of the Complaint, and on that basis denies such averments.

Count XI- Infringement of the '491 Patent by Defendants Torrent Ltd. and Torrent Inc.

95. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 95 of the Complaint, and on that basis denies such averments.

96. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 96 of the Complaint, and on that basis denies such averments.

97. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 97 of the Complaint, and on that basis denies such averments.

98. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 98 of the Complaint, and on that basis denies such averments.

99. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 99 of the Complaint, and on that basis denies such averments..

100. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 100 of the Complaint, and on that basis denies such averments.

101. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 101 of the Complaint, and on that basis denies such averments.

Count XII- Infringement of the '940 Patent by Defendants Torrent Ltd. and Torrent Inc.

102. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 102 of the Complaint, and on that basis denies such averments.

103. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 103 of the Complaint, and on that basis denies such averments.

104. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 104 of the Complaint, and on that basis denies such averments.

105. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 105 of the Complaint, and on that basis denies such averments.

106. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 106 of the Complaint, and on that basis denies such averments.

107. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 107 of the Complaint, and on that basis denies such averments.

108. Sun Ltd. lacks knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 108 of the Complaint, and on that basis denies such averments.

First Affirmative Defense

Noninfringement of the '940 Patent

1. The Sun Ltd. product which is the subject of ANDA 79-057 does not infringe the '940 patent.

Second Affirmative Defense

Invalidity of the '940 Patent

2. The claims of the '940 patent are invalid for failing to meet the requirements of 35 U.S.C. §§ 102, 103 and 112.

Third Affirmative Defense

3. Plaintiffs have failed to state a claim on which relief can be granted. Sun Ltd. reserves the right to assert additional affirmative defenses.

Prayer for Relief

WHEREFORE, Sun Ltd. respectfully requests that this Court:

A. Deny the Plaintiff's requested relief and dismiss the Complaint with prejudice against Sun Ltd.

B. Order that the effective date of the approval of Sun Ltd.'s ANDA 79-057 is immediate pursuant to § 505(j) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j), upon a statement by the FDA that it is otherwise ready to approve the ANDA.

C. Declare that Sun Ltd. has not infringed any asserted claim of the '940 patent;

- D. Declare that the '940 patent invalid.
- E. Award attorneys' fees, interest, and costs, and such other further relief as the Court deems just and proper.

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Dated: October 29, 2007
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*Attorneys for Defendants
Sun Pharmaceutical Industries, Inc.
and Sun Pharmaceutical Industries Ltd.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on October 29, 2007, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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